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Niimi et al.

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(54) **BLOOD CIRCULATION SYSTEM**

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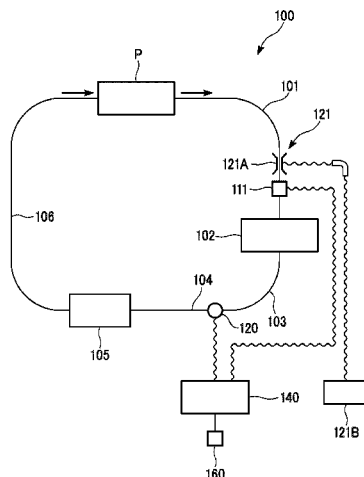
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(57) **ABSTRACT**

Disclosed is an artificial heart and lung apparatus (100) that can be connected to a patient (P), and transfers removed blood to a human body via a roller pump (120), the system including: the roller pump (120); a blood removal line (101) which transfers removed blood to the roller pump (120); a first blood transfer line (104) that transfers blood, which is transferred from the roller pump (120), to the human body; a blood removal rate sensor (111) that is provided in the blood removal line (101); and a control unit (140), in which the control unit (140) performs control such that a blood

(Continued)



transfer rate of the roller pump (120) is in a specific range with respect to a blood removal rate measured by a blood removal rate sensor (111).

5 Claims, 9 Drawing Sheets

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 - A61M 60/38* (2021.01)
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 - See application file for complete search history.

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FIG. 1

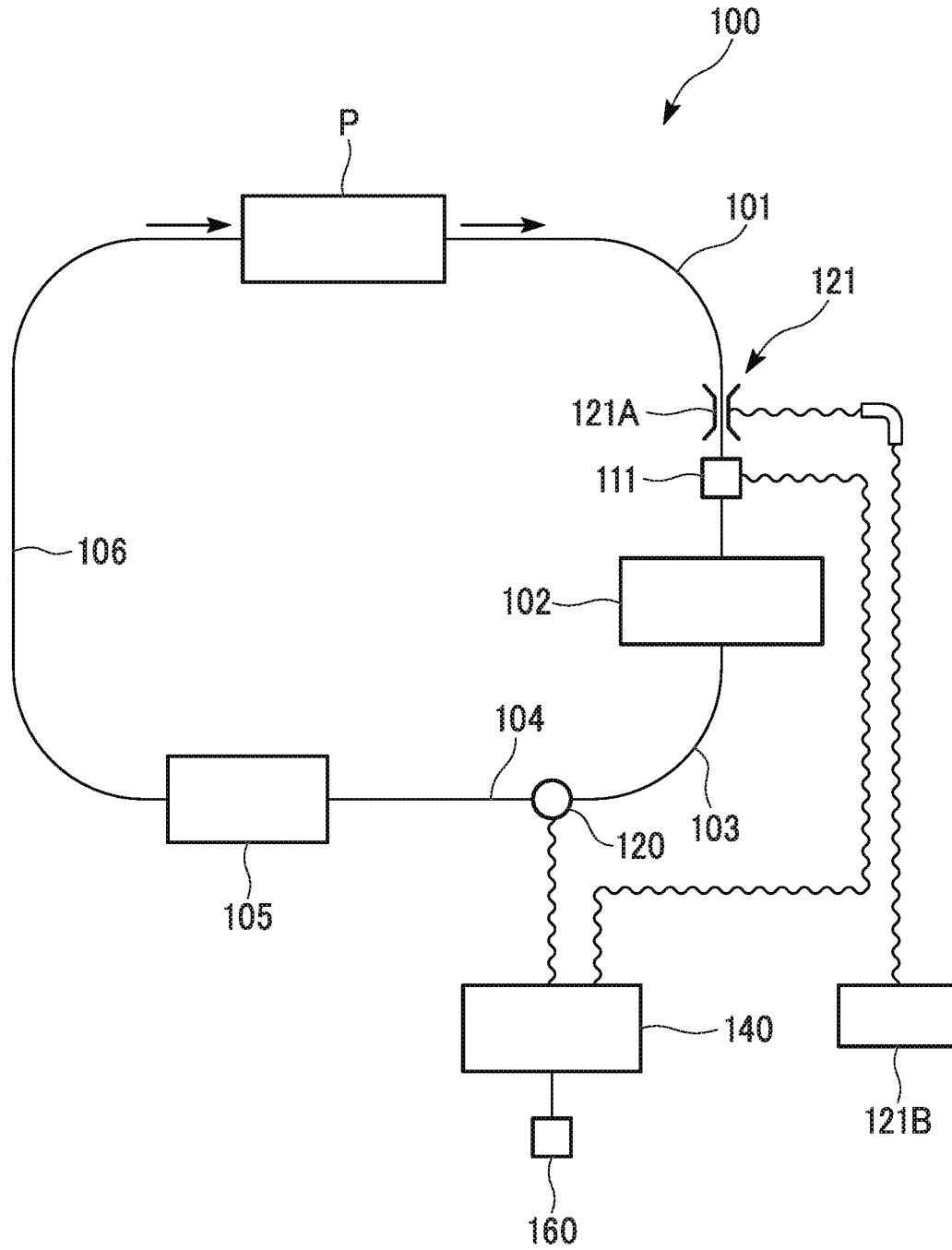


FIG. 2

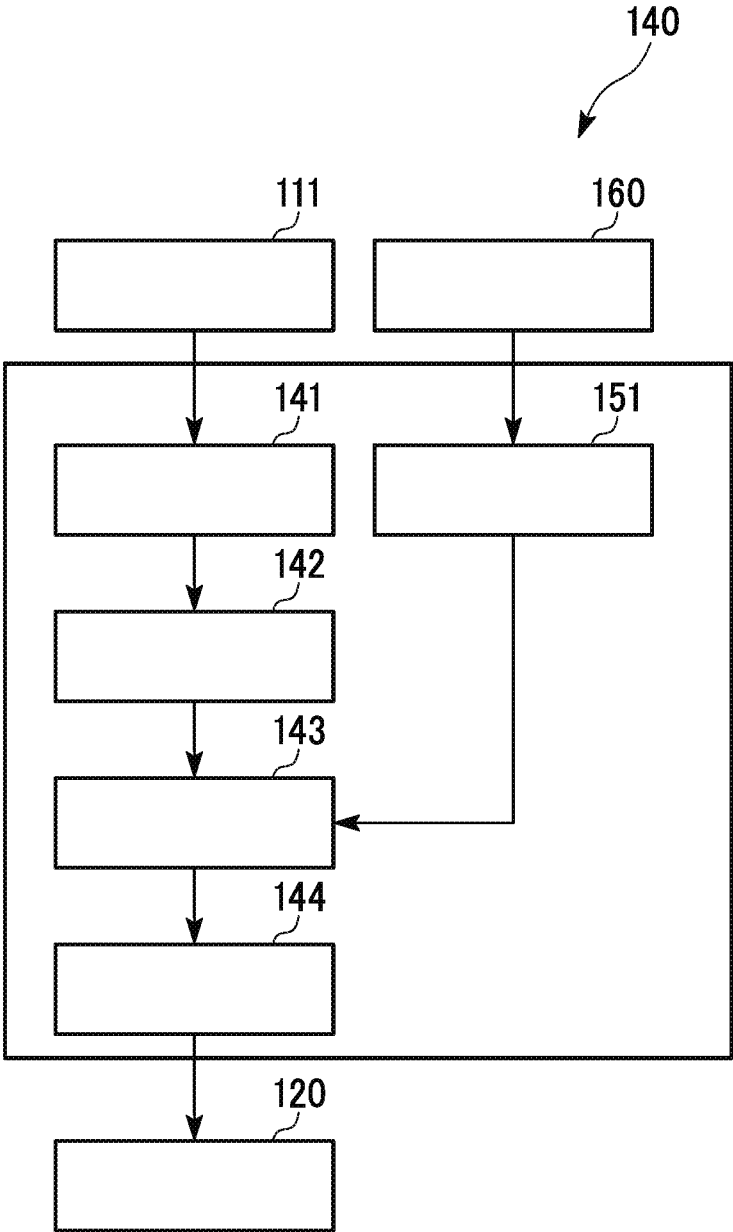


FIG. 3

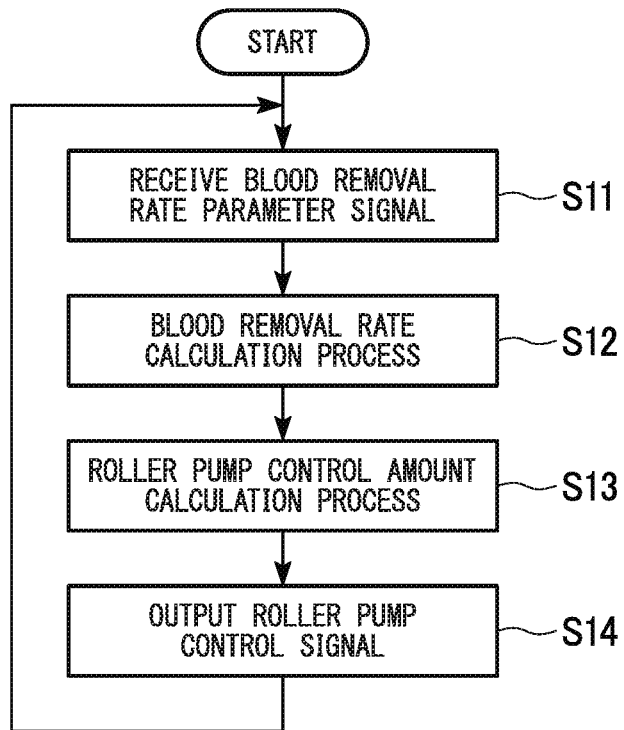


FIG. 4

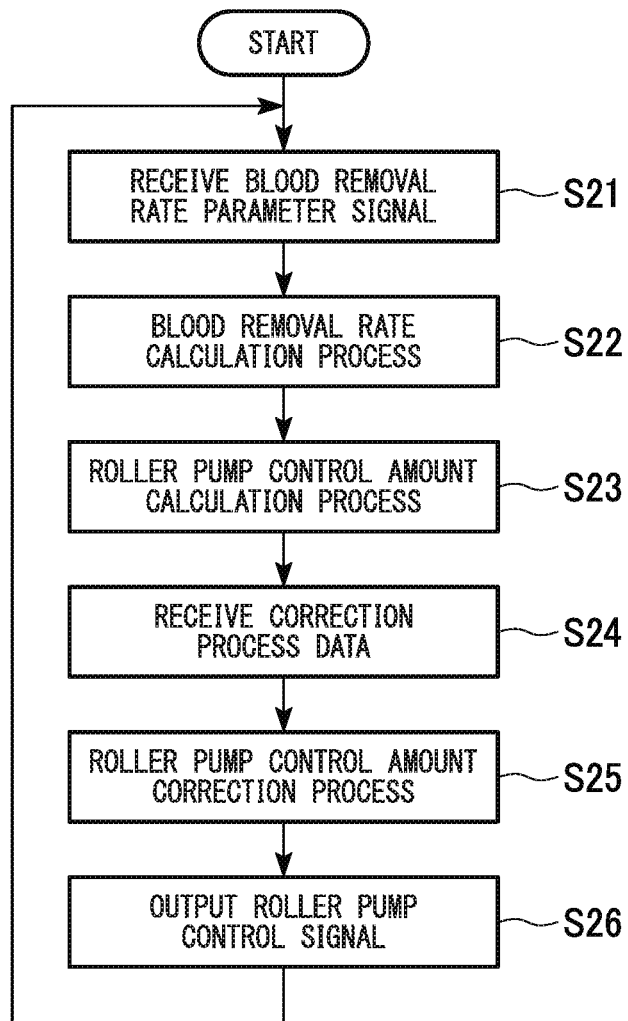


FIG. 5

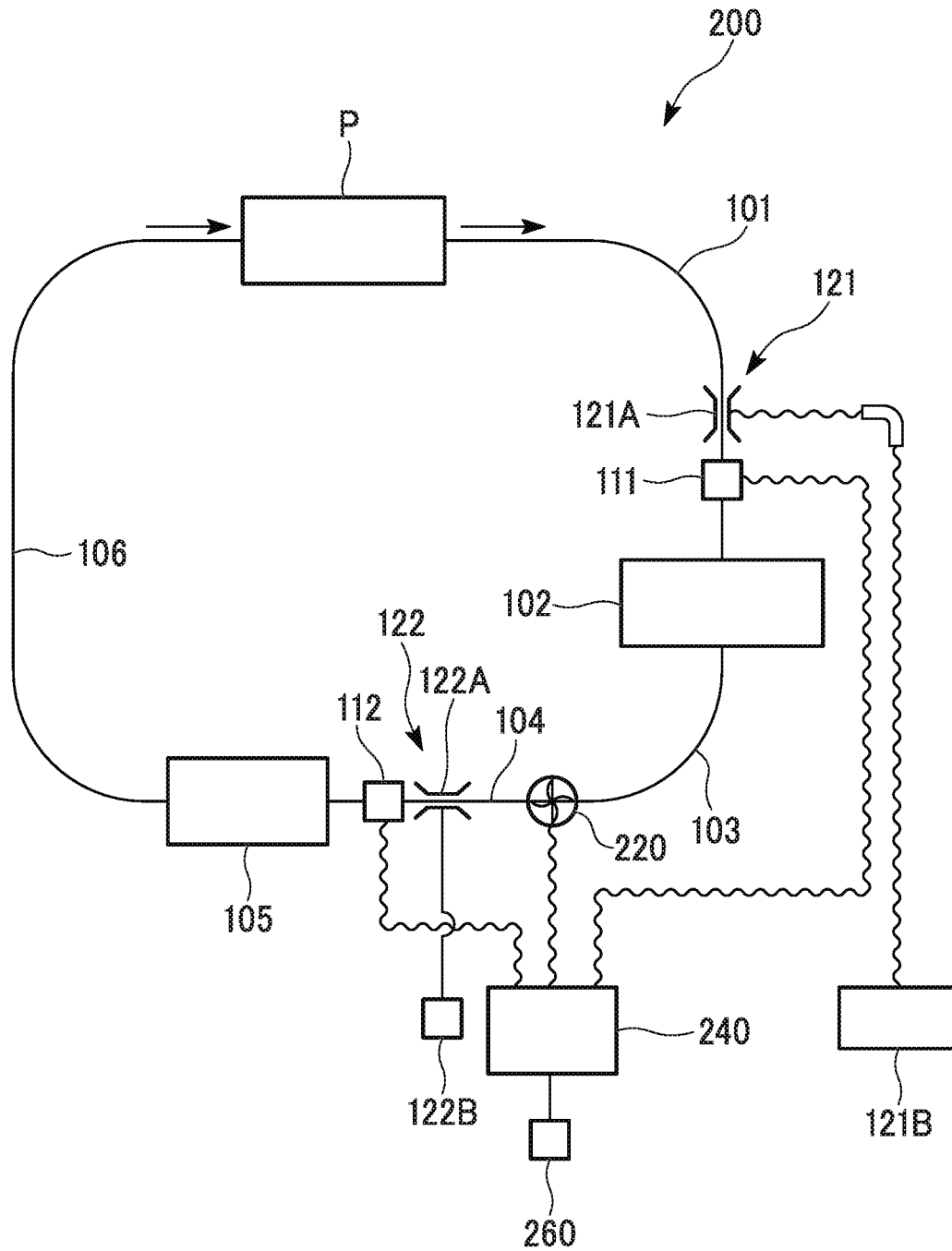


FIG. 6

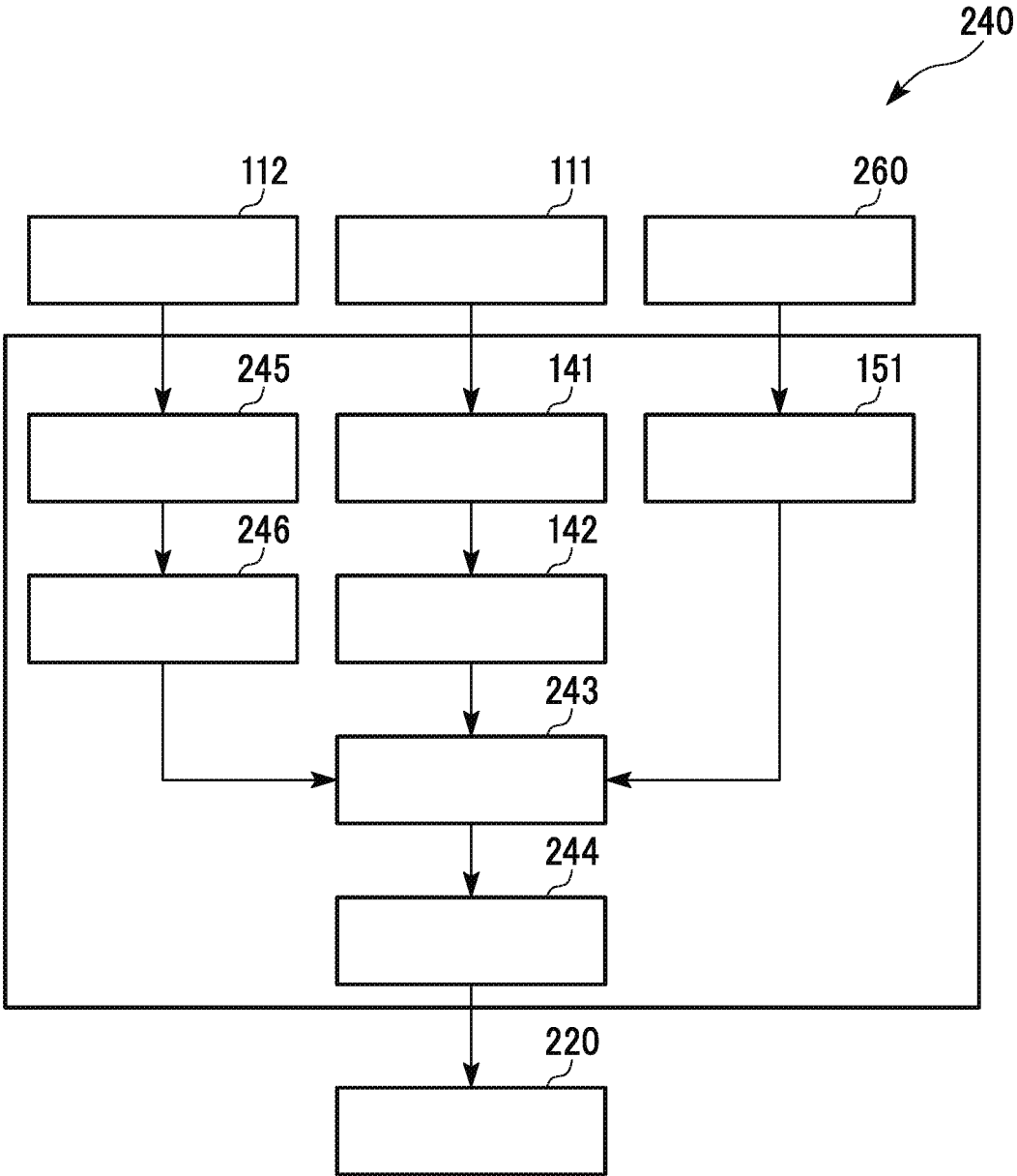


FIG. 7

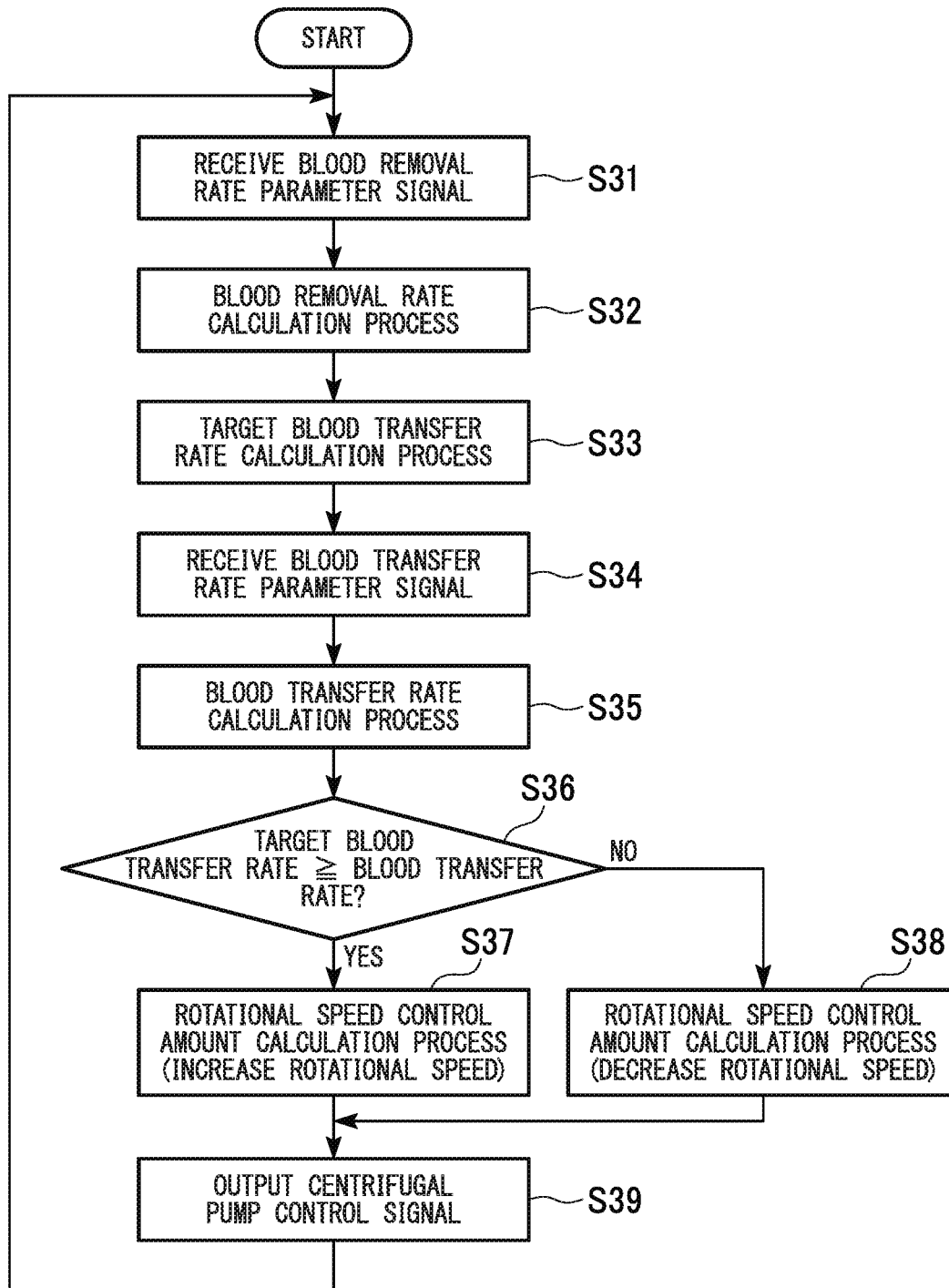


FIG. 8

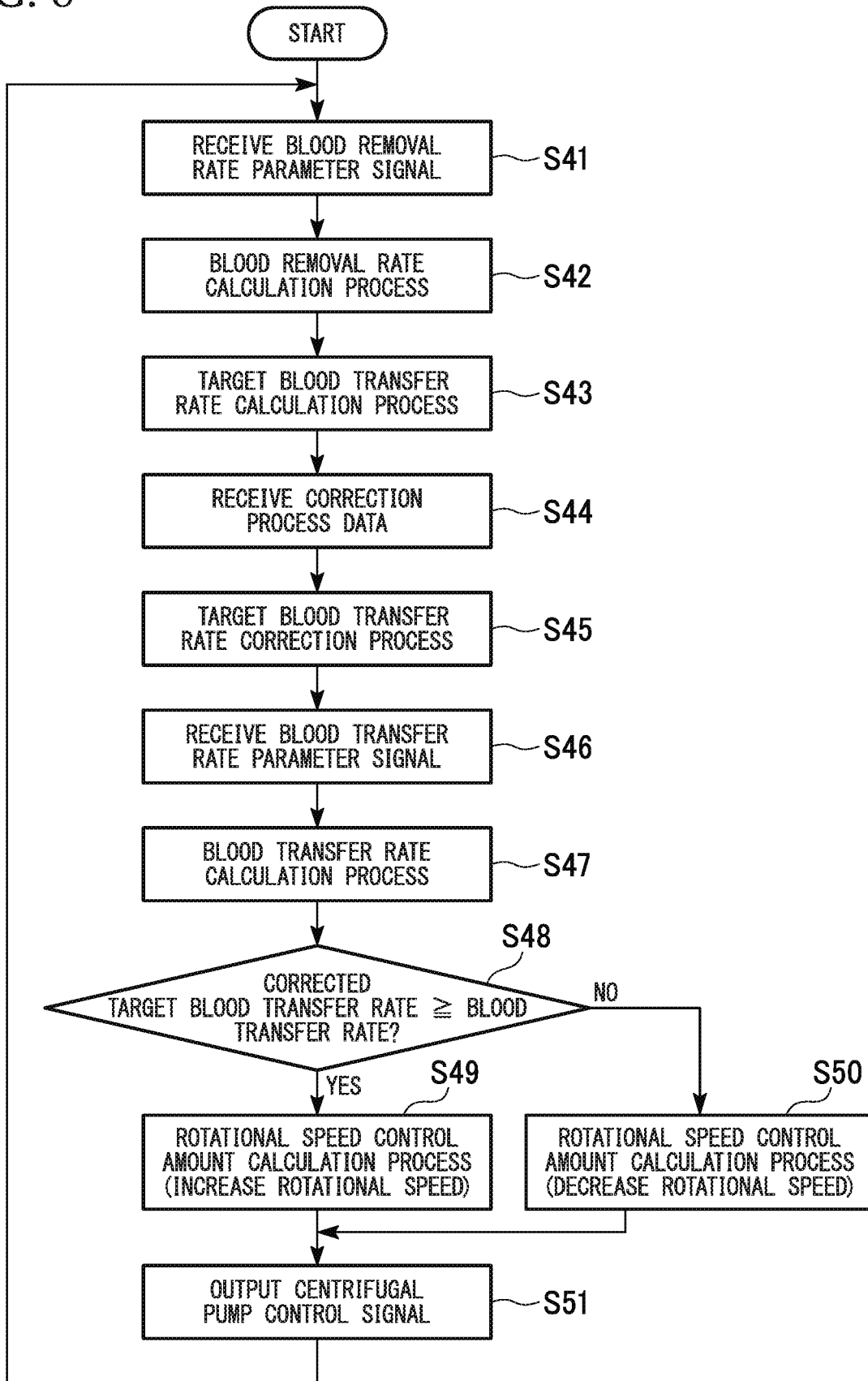
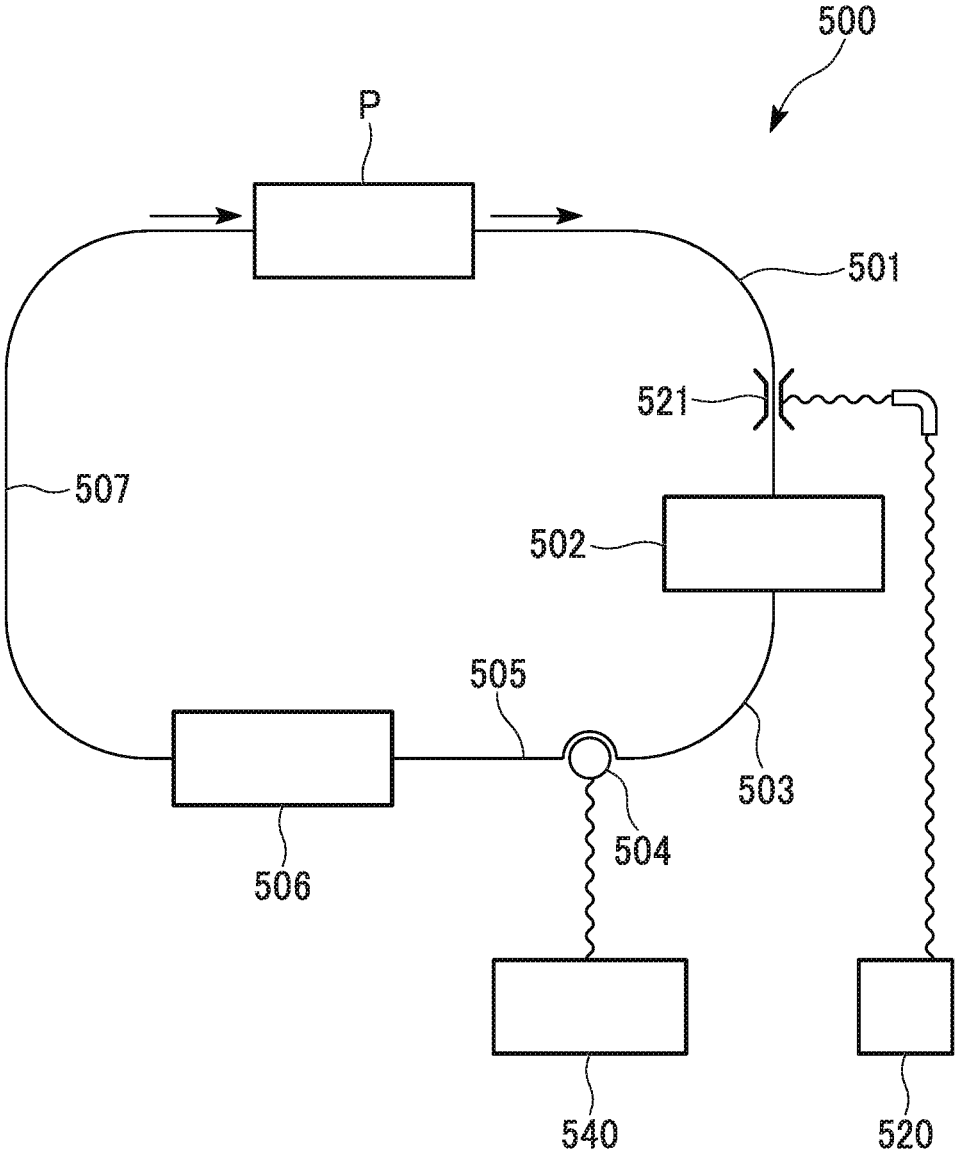


FIG. 9



BLOOD CIRCULATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present invention relates to a blood circulation system that circulates removed blood via a blood transfer pump. This application is a U.S. National Stage entry of PCT Application No. PCT/JP2015/073428, filed on Aug. 20, 2015, which claims priority to Japanese Patent Application No. 2014-167559, filed Aug. 20, 2014, and Japanese Patent Application No. 2015-53600, filed Mar. 17, 2015, the contents of which are incorporated herein by reference.

TECHNICAL FIELD

The present invention relates to a blood circulation system that circulates removed blood via a blood transfer pump. Priority is claimed on Japanese Patent Application No. 2014-167559, filed Aug. 20, 2014, and Japanese Patent Application No. 2015-53600, filed Mar. 17, 2015, the contents of which are incorporated herein by reference.

BACKGROUND ART

In the related art, an artificial heart and lung and a blood circulation system for adjunctively circulating blood are widely used as necessary when a heart is stopped or is approximately stopped during or after a surgery such as cardiac surgery.

As shown in FIG. 9, an artificial heart and lung apparatus (blood circulation system) **500** equipped with an artificial heart and lung in the related art includes a blood removal line **501**; a reservoir **502**; a blood line **503**; a blood transfer line **504**; a first blood transfer line **505**; an artificial lung **506**; and a second blood transfer line **507**.

The blood removal line **501** transfers blood, which has been received from a vein of a patient (human body) P, to the reservoir **502**. The blood removal line **501** is a tube formed of resin such as polyvinyl chloride.

The reservoir **502** includes a tank therein, and temporarily stores the transferred blood.

The blood transfer pump **504** transfers the blood stored in the reservoir **502** to the artificial lung **506** via the blood line **503** through which the reservoir **502** is connected to the blood transfer pump **504**, and via the first blood transfer line **505** through which the blood transfer pump **504** is connected to the artificial lung **506**. For example, a roller pump or a centrifugal pump is used as the blood transfer pump **504**. The blood transfer pump **504** is controlled by a signal output from a blood transfer pump control unit **540**.

The artificial lung **506** includes a hollow fiber membrane, a flat membrane, or the like having good gas permeability, and has the function of discharging carbon dioxide from and adding oxygen to blood.

The second blood transfer line **507** receives the blood, from which carbon dioxide has been discharged and to which oxygen has been added by the artificial lung **506**, and transfers the blood to an artery of the patient P.

Advanced knowledge and techniques are required to operate the artificial heart and lung apparatus **500** with such a configuration. Typically, a clinical engineer adjusts a blood flow rate via a manual operation according to a doctor's instructions.

When adjusting the blood flow rate via a manual operation, the clinical engineer is required to adjust a blood flow rate in the blood removal line **501** by pinching the blood

removal line **501** with a forceps while confirming the degree of removal of blood or an arterial pressure of the patient.

Since the clinical engineer adjusts the amount of discharge of the blood transfer pump by manually controlling the rotational speed of the blood transfer pump (roller pump or centrifugal pump) when adjusting the blood flow rate, a complex and advanced operation technique is required in addition to the adjustment of each line.

Patent Document 1 discloses technology to adjust a blood removal rate in which the blood removal line **501** is pinched and deformed to accurately and simply adjust the blood removal rate via an artificial heart and lung apparatus.

In order to adjust the flow rate of blood to be removed via the blood removal line **501**, the artificial heart and lung apparatus disclosed in Patent Document 1 pinches and deforms the blood removal line **501** by operating a blood removal regulator **521**, which includes a clamper formed of a pair of clamp members and a servo motor, via a blood removal regulator operation unit **520**.

Patent Document 2 discloses technology in which a blood removal regulator control unit is interlocked with a blood transfer regulator control unit, a blood removal rate and a blood transfer rate are simultaneously controlled via operation of one of the control units, and thus a blood flow rate of an artificial heart and lung apparatus is efficiently adjusted.

CITATION LIST

Patent Document

[Patent Document 1] Japanese Unexamined Patent Application, First Publication No. 62-027966

[Patent Document 2] Japanese Unexamined Patent Application, First Publication No. 2006-020712

SUMMARY OF INVENTION

Technical Problem

The amount of blood to be removed may change depending on surgical situations, and it may be difficult to promptly and stably transfer an amount of blood corresponding to a blood removal rate in a case where the blood removal rate changes significantly.

A blood circulation system which circulates removed blood via a blood transfer pump requires technology by which blood is stably circulated at a suitable flow rate.

The present invention is made in light of this problem, and an object of the present invention is to provide a blood circulation system that is capable of stably circulating removed blood at a suitable flow rate via a blood transfer pump.

Solution to Problem

In order to solve this problem, the present invention proposes the following means.

According to a first aspect of the present invention, there is provided a blood circulation system that can be connected to a human body, and transfers removed blood to the human body via a blood transfer pump, the system, including: the blood transfer pump; a blood removal line through which removed blood flows to the blood transfer pump; a blood transfer line that transfers blood, which is sent from the blood transfer pump, to the human body; blood removal rate measurement means that is provided in the blood removal

line; and a control unit, in which, according to a blood removal rate parameter measured by the blood removal rate measurement means, the control unit controls a blood transfer rate of the blood transfer pump such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

In the blood circulation system of the invention, according to the blood removal rate parameter measured by the blood removal rate measurement means, the control unit controls the blood transfer rate of the blood transfer pump such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line. Therefore, it is possible to ensure that the blood transfer rate is in the specific range with respect to the blood removal rate.

As a result, even if the blood removal rate changes, it is possible to transfer an amount of blood to the human body at a blood removal rate in a specific range, and it is possible to stably circulate blood at a suitable flow rate.

In the present invention, the blood removal line represents a blood line among blood lines of the blood circulation system which is formed such that blood removed from the human body flows through the blood line toward the blood transfer pump. More specifically, the blood removal line represents a blood line leading toward a reservoir. The blood transfer line represents a blood line leading toward the human body from the blood transfer pump.

In a blood circulation path, a blood line, which is positioned on the downstream side of a portion (for example, reservoir) in which blood opens to a space and the blood line in which there is always no continuity of a blood flow rate, may not represent the blood removal line or the blood transfer line.

For the sake of convenience, a blood line may indicate a portion of the blood removal line and the blood transfer line.

In the present invention, the specific range with respect to the blood removal rate implies that the blood transfer rate is in a range which is set with respect to the blood removal rate. The amount of deviation of the blood transfer rate with respect to the blood removal rate is represented by a difference in flow rate (for example, an upper limit or lower limit difference in flow rate) with respect to the blood removal rate.

In the present invention, needless to say, the blood removal rate measurement means includes measurement means for measuring a blood removal rate, and includes measurement means for measuring various blood removal rate parameters for specifying a blood removal rate.

Needless to say, the blood removal rate parameters include a blood removal rate, and are parameters which change corresponding to a blood removal rate. That is, the blood removal rate parameters include various parameters for specifying a blood removal rate, for example, the flow speed of removed blood in a case where a cross-sectional flow path area of the blood removal line is already known, and a parameter (for example, a change in ultrasonic wave frequency) for specifying the flow speed.

In the present invention, in a case where according to the blood removal rate parameter, control is performed such that the blood transfer rate is in a specific range with respect to the blood removal rate, the blood removal rate may not be calculated and the blood transfer pump may be directly controlled according to a measured value of the blood removal rate parameter.

According to a second aspect of the present invention, in the first aspect, according to the blood removal rate parameter measured by the blood removal rate measurement means, the control unit controls the blood transfer rate of the blood transfer pump such that the transfer rate of blood flowing through the blood transfer line is synchronized with the removal rate of blood flowing through the blood removal line.

In the blood circulation system of the invention, according to the blood removal rate parameter measured by the blood removal rate measurement means, the control unit controls the blood transfer rate of the blood transfer pump such that the transfer rate of blood flowing through the blood transfer line is synchronized with the removal rate of blood flowing through the blood removal line. Therefore, it is possible to transfer the same amount of blood as the amount of removed blood to the human body.

As a result, even if the blood removal rate changes, it is possible to transfer the same amount of blood as the amount of removed blood to the human body, and it is possible to stably circulate blood at a suitable flow rate.

In the present invention, the synchronization of the transfer rate of blood flowing through the blood transfer line with the removal rate of blood flowing through the blood removal line implies that the blood transfer rate of the blood transfer pump is controlled to be the same as the blood removal rate. That is, errors caused by a time lag of a control signal output to the blood transfer pump or a response time of the blood transfer pump are allowed.

The synchronization includes not only a case in which the blood removal rate exactly coincides with the blood transfer rate, but also a case in which the blood removal rate substantially coincides with the blood transfer rate.

The synchronization includes a case in which the same amount of blood as the amount of removed blood is transferred by the blood transfer pump while the transferring of blood is delayed by an amount of time set in advance.

According to a third aspect of the present invention, the first and second aspects further include a correction process setting unit, in which, according to correction process data input to the correction process setting unit, the control unit performs correction such that the blood transfer rate of the blood transfer pump corresponds to the blood removal rate.

In the blood circulation system of the invention, the correction process setting unit is provided, and according to the correction process data input to the correction process setting unit, the control unit performs correction such that the blood transfer rate of the blood transfer pump corresponds to the blood removal rate. In a case where a combination of the blood removal rate measurement means and the blood transfer pump is changed, and the blood transfer rate of the blood transfer pump controlled by the blood removal rate parameter does not correspond to the blood removal rate due to individual variations of the blood removal rate measurement means and the blood transfer pump, the blood transfer rate can be efficiently corrected to correspond to the blood removal rate.

According to a fourth aspect of the present invention, the first to third aspects further include a roller pump that is the blood transfer pump, in which the control unit controls the rotational speed of the roller pump according to the blood removal rate parameter measured by the blood removal rate measurement means.

In the blood circulation system of the invention, the roller pump is included as the blood transfer pump, and the control unit controls the rotational speed of the roller pump according to the blood removal rate parameter measured by the

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blood removal rate measurement means. As a result, the blood circulation system is prevented from being affected by pressure, and it is possible to ensure a stable blood transfer rate by controlling the rotational speed.

According to a fifth aspect of the present invention, the first to third aspects further include blood transfer rate measurement means that is provided in the blood transfer line, in which the control unit controls the blood transfer pump by comparison of a blood transfer rate parameter measured by the blood transfer rate measurement means with the blood removal rate parameter measured by the blood removal rate measurement means.

In the blood circulation system of the invention, the blood transfer rate measurement means is provided in the blood transfer line, and the control unit controls the blood transfer pump by comparison of the blood transfer rate parameter measured by the blood transfer rate measurement means with the blood removal rate parameter measured by the blood removal rate measurement means. Therefore, it is possible to efficiently reduce the difference between the blood transfer rate and the blood removal rate.

As a result, it is possible to efficiently make the blood transfer rate correspond to the blood removal rate, and it is possible to perform stable blood circulation.

In the present invention, needless to say, the blood transfer rate measurement means includes measurement means for measuring a blood transfer rate, and includes measurement means for measuring various blood transfer rate parameters for specifying a blood transfer rate.

Needless to say, the blood transfer rate parameters include a blood transfer rate, and are parameters which change corresponding to a blood transfer rate. That is, the blood transfer rate parameters include various parameters for specifying a blood removal rate, for example, the flow speed of transferred blood in a case where a cross-sectional flow path area of the blood transfer line is already known, and a parameter (for example, a change in ultrasonic wave frequency) for specifying the flow speed.

A comparison between a blood transfer rate parameter and a blood removal rate parameter implies any one of a comparison therebetween in a case where the types of the blood transfer rate parameter and the blood removal rate parameter are the same, a direct comparison therebetween in a case where the types of the blood transfer rate parameter and the blood removal rate parameter are different from each other, and a comparison therebetween after one or both of the blood transfer rate parameter and the blood removal rate parameter are converted into forms in which both can be compared to each other.

According to a sixth aspect of the present invention, the fifth aspect further includes a centrifugal pump that is the blood transfer pump, in which the control unit controls the rotational speed of the centrifugal pump.

In the blood circulation system of the invention, the centrifugal pump is included as the blood transfer pump, and the control unit controls the rotational speed of the centrifugal pump by the comparison of the blood transfer rate parameter measured by the blood transfer rate measurement means with the blood removal rate parameter measured by the blood removal rate measurement means. As a result, it is possible to promptly and stably transfer blood, the transfer rate of which corresponds to a blood removal rate.

According to a seventh aspect of the present invention, in the first to sixth aspects, flow rate adjustment means is provided in the blood removal line.

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In the blood circulation system of the invention, the flow rate adjustment means is provided in the blood removal line, and thus, it is possible to efficiently adjust the blood removal rate.

According to an eighth aspect of the present invention, in the first to third, fifth and sixth aspects, flow rate adjustment means is provided in both the blood removal line and the blood transfer line.

In the blood circulation system of the invention, the flow rate adjustment means is provided in both the blood removal line and the blood transfer line, and thus, it is possible to efficiently adjust a blood flow rate. If the blood transfer pump is a centrifugal pump, it is possible to prevent the back flowing of blood when the centrifugal pump stops.

Advantageous Effects of Invention

The blood circulation system of the invention is capable of transferring blood such that the blood transfer rate of the blood transfer pump corresponds to the blood removal rate.

As a result, even if the blood removal rate changes, it is possible to stably circulate blood at a suitable flow rate.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a circuit diagram showing a schematic configuration of an artificial heart and lung apparatus of a first embodiment of the present invention.

FIG. 2 is a block diagram showing a schematic configuration of a control unit of the artificial heart and lung apparatus of the first embodiment of the present invention.

FIG. 3 is a flowchart showing an operational sequence of the control unit in a case where a correction process is not performed in the artificial heart and lung apparatus of the first embodiment of the present invention.

FIG. 4 is a flowchart showing an operational sequence of the control unit in a case where a correction process is performed in the artificial heart and lung apparatus of the first embodiment of the present invention.

FIG. 5 is a circuit diagram showing a schematic configuration of an artificial heart and lung apparatus of a second embodiment of the present invention.

FIG. 6 is a block diagram showing a schematic configuration of a control unit of the artificial heart and lung apparatus of the second embodiment of the present invention.

FIG. 7 is a flowchart showing an operational sequence of the control unit in a case where a correction process is not performed in the artificial heart and lung apparatus of the second embodiment of the present invention.

FIG. 8 is a flowchart showing an operational sequence of the control unit in a case where a correction process is performed in the artificial heart and lung apparatus of the second embodiment of the present invention.

FIG. 9 is a circuit diagram showing a schematic configuration of an artificial heart and lung apparatus in the related art.

DESCRIPTION OF EMBODIMENTS

First Embodiment

Hereinafter, an artificial heart and lung apparatus (blood circulation system) of a first embodiment of the present invention will be described with reference to FIGS. 1 to 3.

FIG. 1 is a circuit diagram showing a schematic configuration of the artificial heart and lung apparatus of the first

embodiment of the present invention. Reference sign **100** represents an artificial heart and lung apparatus, reference sign **111** represents a blood removal rate sensor, reference sign **120** represents a roller pump, reference sign **140** represents a control unit, and reference sign **160** represents a correction process setting unit.

As shown in FIG. 1, the artificial heart and lung apparatus **100** includes a blood removal line **101**; a reservoir **102**; a blood line **103**; a first blood transfer line (blood transfer line) **104**; an artificial lung **105**; a second blood transfer line (blood transfer line) **106**; a blood removal rate sensor (blood removal rate measurement means) **111**; a roller pump (blood transfer pump) **120**; a blood removal regulator (flow rate adjustment means) **121**; a control unit **140**; and a correction process setting unit **160**.

The blood removal line **101**, the reservoir **102**, the blood line **103**, the roller pump **120**, the first blood transfer line **104**, the artificial lung **105**, and the second blood transfer line **106** are connected together in the listed sequence. The blood removal regulator **121** and the blood removal rate sensor **111** are disposed in the blood removal line **101** in the listed sequence.

Blood to be removed via the blood removal line **101** is circulated to a patient (human body) P via the first blood transfer line **104** and the second blood transfer line **106**.

The blood removal line **101** is a tube formed of resin such as polyvinyl chloride. One end of the blood removal line **101** can be connected to the patient P, and transfers blood, which has been received from a vein, to the reservoir **102**.

A sensor or the like (not shown) is provided in the blood removal line **101** so as to monitor the concentration of blood or the concentration of oxygen as necessary. The sensor or the like may be provided in the blood line **103** or the first blood transfer line **104** instead of the blood removal line **101**.

The reservoir **102** includes a tank therein, and temporarily stores the transferred blood.

A suction line (not shown) is connected to the reservoir **102** so as to suction blood in a surgical site of the patient P, and a vent line (not shown) is connected to the reservoir **102** so as to suction blood in a right cardiac chamber.

The blood line **103** has the same configuration as that of the blood removal line **101**. The upstream side of the blood line **103** is connected to the reservoir **102**, and the downstream side of the blood line **103** is connected to the roller pump **120**. The blood line **103** transfers the blood, which has been received from the reservoir **102**, to the roller pump **120**.

The roller pump **120** includes a rotating roller and a tube that is disposed on the outside of the rotating roller and is formed of flexible resin. If the rotating roller rotates and wipes the tube, and blood is suctioned and transferred out, the blood stored in the reservoir **102** is suctioned via the blood line **103**, and is transferred to the artificial lung **105** via the first blood transfer line **104**.

The rotational speed of the rotating roller is controlled by a rotation control signal output from the control unit **140**, and the roller pump **120** suctioned and transfers the amount of blood corresponding to the rotational speed of the rotating roller.

The first blood transfer line **104** has the same configuration as that of the blood removal line **101**. The upstream side of the first blood transfer line **104** is connected to the roller pump **120**, and the downstream side of the first blood transfer line **104** is connected to the artificial lung **105**. The first blood transfer line **104** transfers the blood, which has been transferred out from the roller pump **120**, to the artificial lung **105**.

The artificial lung **105** includes a hollow fiber membrane, a flat membrane, or the like having good gas permeability, and discharges carbon dioxide from and adds oxygen to blood.

A heat exchanger is formed integrally with the artificial lung **105** so as to adjust the temperature of blood.

The second blood transfer line **106** has the same configuration as that of the blood removal line **101**, and receives the blood, from which carbon dioxide has been discharged and to which oxygen has been added, from the artificial lung **105**, and transfers the blood to an artery of the patient P.

A filter (not shown) is provided in the second blood transfer line **106** so as to remove foreign matter such as thrombi and bubbles from blood.

The blood removal regulator **121** is provided in the blood removal line **101**. The blood removal regulator **121** includes a clamber **121A** formed of a pair of clamp members; a servo motor (not shown) that operates the clamber **121A**; and a blood removal regulator operation unit **121B**. An operator changes the cross-sectional area of the blood removal line **101** by adjusting the amount of clamp (the amount of pinch) of the clamber **121A** via the servo motor driven by manually operating the blood removal regulator operation unit **121B**, and as a result, the removal rate of blood flowing through the blood removal line **101** is adjusted.

The blood removal rate sensor (blood removal rate measurement means) **111** is provided in the blood removal line **101**. The blood removal rate sensor **111** transmits a blood removal rate parameter signal, which is measured using an ultrasonic sensor that measures the flow speed of blood via ultrasonic waves, to the control unit **140**.

Hereinafter, a schematic configuration of the control unit **140** will be described with reference to FIG. 2. FIG. 2 is a block diagram showing the schematic configuration of the control unit **140** of the first embodiment.

The control unit **140** includes a blood removal rate parameter signal receiving unit **141**; a blood removal rate calculation unit **142**; a roller pump control amount calculation unit **143**; a roller pump control unit **144**; and a correction process data receiving unit **151**.

The control unit **140** is connected to the blood removal rate sensor **111**, and the correction process setting unit **160**, and the roller pump **120** via cables.

The correction process setting unit **160** is capable of setting correction process data for correcting measurement errors of the blood removal rate sensor **111**, variations of a blood transfer rate characteristic (relationship between the rotational speed and the blood transfer rate) of the roller pump **120** or a deviation of the blood transfer rate with respect to the rotational speed of the roller pump **120** which occurs due to the combination of the blood removal rate sensor **111** and the roller pump **120**, or correcting a temporary increase of the blood transfer rate with respect to the blood removal rate.

The correction process data is preferably defined by the amount of deviation (the amount of offset, a ratio, or the like) of the blood transfer rate with respect to the blood removal rate. Alternatively, the correction process data may be defined by other techniques if the correction process data is capable of setting the blood transfer rate of the roller pump **120** to be in a specific range with respect to the blood removal rate.

In the embodiment, the correction process setting unit **160** outputs a correction process execution instruction indicating the execution of a correction process.

In the embodiment, the correction process data is preferably set according to at least one of the measurement errors

of the blood removal rate sensor **111**, and the amount of a deviation between the blood transfer rate characteristic (relationship between the rotational speed and the blood transfer rate) of the roller pump **120** and a basic blood transfer rate characteristic of the roller pump **120**, all of which are confirmed in advance.

The correction process data may be set according to an increase or decrease in the level of blood in the reservoir **102** which occurs after blood circulation starts.

The blood removal rate parameter signal receiving unit **141** is connected to the blood removal rate sensor **111**, and receives a blood removal rate parameter signal sent from the blood removal rate sensor **111**.

The blood removal rate calculation unit **142** calculates the amount of removed blood according to a signal sent from the blood removal rate parameter signal receiving unit **141**. Specifically, it is possible to calculate a blood removal rate by multiplying a blood removal speed (flow rate parameter), which is calculated from the blood removal rate parameter signal, by a flow path area of the blood removal line **101**.

The correction process data receiving unit **151** receives the correction process data and the correction process execution instruction, which have been set by the correction process setting unit **160**, from the correction process setting unit **160**.

The roller pump control amount calculation unit **143** calculates a rotational speed (according to a basic blood transfer rate characteristic), which is required to synchronize the blood transfer rate of the roller pump **120** with the blood removal rate, according to the blood removal rate received from the blood removal rate calculation unit **142**. It is possible to calculate the rotational speed according to the basic blood transfer rate characteristic via a data table representing the relationship between the rotational speed of the roller pump **120** and the blood transfer rate, or a calculation expression representing the relationship between the rotational speed of the roller pump **120** and the blood transfer rate.

The rotational speed to be output to the roller pump **120** is calculated according to the rotational speed according to the basic blood transfer rate characteristic and the correction process data received from the correction process data receiving unit **151**.

The synchronization of the blood transfer rate of the roller pump **120** with the blood removal rate is one aspect in which the blood transfer rate is controlled to be in a specific range (for example, in a range represented by a ratio to the blood removal rate, or in a range represented by a difference in flow rate with respect to the blood removal rate) with respect to the blood removal rate.

The roller pump control unit **144** outputs a signal, which corresponds to a control amount (corrected rotational speed) received from the roller pump control amount calculation unit **143**, to the roller pump **120**.

Hereinafter, an operational sequence in a case where the control unit **140** of the artificial heart and lung apparatus **100** of the first embodiment does not perform a correction process will be described with reference to FIG. 3. FIG. 3 is a flowchart showing the operational sequence of the control unit **140** in a case where a correction process is not performed in the artificial heart and lung apparatus **100**.

(1) First, the control unit **140** receives a blood removal rate parameter signal (**S11**).

(2) Subsequently, the control unit **140** calculates a blood removal rate according to the received blood removal rate parameter signal (**S12**).

(3) Subsequently, the control unit **140** calculates a control amount (rotational speed) according to a basic blood transfer rate characteristic of the roller pump **120** according to the received blood removal rate (**S13**).

(4) Subsequently, the control unit **140** outputs a signal, which corresponds to the control amount to the roller pump **120** (**S14**).

If **S14** is executed, the process proceeds to **S11**.

S11 to **S14** are repeatedly executed at predetermined intervals until a surgery is complete and blood circulation ends.

Hereinafter, an operational sequence in a case where the control unit **140** of the artificial heart and lung apparatus **100** of the first embodiment performs a correction process will be described with reference to FIG. 4. FIG. 4 is a flowchart showing the operational sequence of the control unit **140** in a case where a correction process is performed in the artificial heart and lung apparatus **100**.

(1) First, the control unit **140** receives a blood removal rate parameter signal (**S21**).

(2) Subsequently, the control unit **140** calculates a blood removal rate according to the received blood removal rate parameter signal (**S22**).

(3) Subsequently, the control unit **140** calculates a rotational speed according to on the basic blood transfer rate characteristic of the roller pump **120** according to the received blood removal rate (**S23**).

(4) Subsequently, the control unit **140** receives correction process data (**S24**).

(5) Subsequently, the control unit **140** corrects the rotational speed, which has been calculated in **S23** according to the basic blood transfer rate characteristic of the roller pump **120**, according to the correction process data, and calculates a control amount (corrected rotational speed) to be output to the roller pump **120** (**S25**).

(6) Subsequently, the control unit **140** outputs a signal which corresponds to the control amount corrected rotational speed), to the roller pump **120** (**S26**).

If **S26** is executed, the process proceeds to **S21**.

S21 to **S26** are repeatedly executed at predetermined intervals until a surgery is complete and blood circulation ends.

In the artificial heart and lung apparatus **100** of the first embodiment, the control unit **140** controls the roller pump **120** such that the blood transfer rate of the roller pump **120** is synchronized with the flow rate of removed blood flowing through the blood removal line **101**. Accordingly, the amount of blood corresponding to the amount of removed blood can be transferred to the patient P via the first blood transfer line **104**, the artificial lung **105**, and the second blood transfer line **106**.

As a result, even if the blood removal rate changes, it is possible to stably circulate blood at a suitable flow rate.

In the artificial heart and lung apparatus **100** of the first embodiment, the correction process setting unit **100** is provided, and the control unit **140** corrects deviations between a measurement characteristic of the blood removal rate sensor **111** and the blood transfer rate characteristic of the roller pump **120** according to correction process data input to the correction process setting unit **160**. Accordingly, the artificial heart and lung apparatus **100** of the first embodiment is capable of efficiently synchronizing the blood transfer rate of the roller pump **120** with the blood removal rate.

Since the artificial heart and lung apparatus **100** of the first embodiment includes the roller pump **120** as the blood transfer pump, the artificial heart and lung apparatus **100** is

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unlikely to be affected by pressure, and is capable of transferring blood at a stable blood transfer rate.

In the artificial heart and lung apparatus **100** of the first embodiment, the blood removal regulator **121** is provided in the blood removal line **101**, and thus, the flow rate of blood removed via the blood removal line **101** is suitably adjusted.

The artificial heart and lung apparatus **100** of the first embodiment includes the reservoir **102**. The artificial heart and lung apparatus **100** is capable of synchronizing a blood transfer rate with a blood removal rate or adjusting the blood transfer rate to be in a specific range with respect to the blood removal rate, and the occurrence of excessive negative pressure is prevented. Accordingly, an auxiliary circulation apparatus (blood circulation system) in which the reservoir **102** is not provided and the roller pump **120** is adopted may be used as the artificial heart and lung apparatus **100** shown in FIG. **1**.

Second Embodiment

Hereinafter, an artificial heart and lung apparatus (blood circulation system) of a second embodiment of the present invention will be described with reference to FIGS. **5** to **8**.

FIG. **5** is a circuit diagram showing a schematic configuration of the artificial heart and lung apparatus of the second embodiment of the present invention. Reference sign **200** represents an artificial heart and lung apparatus, reference sign **112** represents a blood transfer rate sensor (blood transfer rate measurement means), reference sign **220** represents a centrifugal pump (blood transfer pump), reference sign **260** represents a correction process setting unit, and reference sign **240** represents a control unit.

As shown in FIG. **5**, an artificial heart and lung apparatus **200** includes the blood removal line **101**; the reservoir **102**; the blood line **103**; a centrifugal pump **220**; the first blood transfer line (blood transfer line) **104**; the artificial lung **105**; the second blood transfer line (blood transfer line) **106**; the blood removal rate sensor **111**; a blood transfer rate sensor **112**; the blood removal regulator (flow rate adjustment means) **121**; a blood transfer regulator **122**; a control unit **240**; and a correction process setting unit **260**.

The blood removal line **101**, the reservoir **102**, the blood line **103**, the centrifugal pump **220**, the first blood transfer line **104**, the artificial lung **105**, and the second blood transfer line **106** are connected together in the listed sequence. The blood removal regulator **121** and the blood removal rate sensor **111** are disposed in the blood removal line **101** in the listed sequence. The blood transfer regulator **122** and the blood transfer rate sensor **112** are disposed in the first blood transfer line **104** in the listed sequence.

The blood removal line **101**, the reservoir **102**, the blood line **103**, the first blood transfer line **104**, the artificial lung **105**, the second blood transfer line **106**, the blood removal rate sensor **111**, and the blood removal regulator **121** are the same as those of the first embodiment, and thus, a description thereof will be omitted.

Similar to the blood removal rate sensor **111**, an ultrasonic sensor is used as the blood transfer rate sensor (blood transfer rate measurement means) **112**. The blood transfer rate sensor **112** sends a measurement result to the control unit **240**.

The centrifugal pump **220** suctions blood stored in the reservoir **102** via the blood line **103**, and transfers the blood to the artificial lung **105** via the first blood transfer line **104** by rotating impeller blades via an AC servo motor or a DC servo motor.

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The rotational speed of the centrifugal pump **220** is feedback controlled such that a blood transfer rate measured by the blood transfer rate sensor **112** is synchronized with a blood removal rate measured by the blood removal rate sensor **111**.

The blood transfer regulator **122** is provided in the first blood transfer line **104**. The blood transfer regulator **122** includes a clasper **122A** formed of a pair of clamp members; a servo motor (not shown) that operates the clasper **122A**; and a blood transfer regulator operation unit **122B**. An operator blocks the first blood transfer line **104** by adjusting the amount of clamp (the amount of pinch) of the clasper **122A** via the servo motor driven by manually operating the blood transfer regulator operation unit **122B**, and thus, the back flowing of blood when the centrifugal pump **220** stops is prevented.

Hereinafter, a schematic configuration of the control unit **240** will be described with reference to FIG. **6**. FIG. **6** is a block diagram showing the schematic configuration of the control unit **240** of the second embodiment.

The control unit **240** includes the blood removal rate parameter signal receiving unit **141**; the blood removal rate calculation unit **142**; a centrifugal pump control amount calculation unit **243**; a centrifugal pump control unit **244**; a blood transfer rate parameter signal receiving unit **245**; a blood transfer rate calculation unit **246**; and the correction process data receiving unit **151**.

The control unit **240** is connected to the blood removal rate sensor **111**, the blood transfer rate sensor **112**, the correction process setting unit **260**, and the centrifugal pump **220** via cables.

The blood removal rate parameter signal receiving unit **141**, the blood removal rate calculation unit **142**, and the correction process data receiving unit **151** are the same as those of the first embodiment, and thus, a description thereof will be omitted.

Since the centrifugal pump **220** of the second embodiment is feedback controlled, there is a low need to take into consideration blood transfer rate errors which are caused by a blood transfer rate characteristic. In contrast, the blood removal rate sensor **111** and the blood transfer rate sensor **112** have different measurement characteristics. If the measurement characteristics (measurement errors) of the blood removal rate sensor **111** and the blood transfer rate sensor **112** are different from each other, a deviation between a blood transfer rate and a blood removal rate may occur due to the combination of the blood removal rate sensor **111** and the blood transfer rate sensor **112**. The deviation between the blood transfer rate and the blood removal rate occurring due to the combination of the blood removal rate sensor **111** and the blood transfer rate sensor **112** is preferably corrected.

The correction process setting unit **260** sets correction process data for correcting a deviation occurring due to the combination of the blood removal rate sensor **111** and the blood transfer rate sensor **112**, or correcting a temporary increase of the blood transfer rate with respect to the blood removal rate.

The correction process data is preferably defined by the amount of deviation (the amount of offset, a ratio, or the like) of the blood transfer rate with respect to the blood removal rate. Alternatively, the correction process data may be defined by other techniques if the correction process data is capable of setting the blood transfer rate of the centrifugal pump **220** to be in a specific range with respect to the blood removal rate. In the embodiment, the correction process setting unit **260** outputs a correction process execution instruction indicating the execution of a correction process.

In the embodiment, the correction process data is preferably set according to the amount of a deviation between the measurement characteristic of the blood removal rate sensor **111** and the measurement characteristic of the blood transfer rate sensor **112** which have been confirmed in advance.

The correction process data may be set according to an increase or decrease in the level of blood in the reservoir **102** which occurs after blood circulation starts.

The blood transfer rate parameter signal receiving unit **245** is connected to the blood transfer rate sensor **112**, and receives a blood transfer rate parameter signal sent from the blood transfer rate sensor **112**.

The blood transfer rate calculation unit **246** calculates a blood transfer rate according to a signal sent from the blood transfer rate parameter signal receiving unit **245**. Specifically, it is possible to calculate a blood removal rate by multiplying a blood transfer speed (flow rate parameter), which is calculated from the blood transfer rate parameter signal, by a flow path area of the first blood transfer line **104**.

First, the centrifugal pump control amount calculation unit **243** calculates a target blood transfer rate, which is required to synchronize the blood transfer rate of the centrifugal pump **220** with the blood removal rate, according to the blood removal rate received from the blood removal rate calculation unit **142**. Subsequently, a corrected target blood transfer rate is calculated by correcting the target blood transfer rate according to the correction process data received from the correction process data receiving unit **151**. The centrifugal pump control amount calculation unit **243** increases or decreases a control amount (corrected rotational speed) to be output to the centrifugal pump **220** by comparing the corrected target blood transfer rate to the blood transfer rate received from the blood transfer rate calculation unit **246**.

The synchronization of the blood transfer rate of the centrifugal pump **220** with the blood removal rate is one aspect in which the blood transfer rate is controlled to be in a specific range (for example, in a range represented by a ratio to the blood removal rate, or in a range represented by a difference in flow rate with respect to the blood removal rate) with respect to the blood removal rate.

In a case where the correction process is not performed, and there is no deviation between the measurement characteristics, the centrifugal pump **220** may be controlled via a rotational speed.

The correction process data receiving unit **151** receives the correction process data and the correction process execution instruction, which have been set by the correction process setting unit **260**, from the correction process setting unit **260**.

The centrifugal pump control unit **244** outputs a signal, which corresponds to the rotational speed, to the centrifugal pump **220** according to the control amount (corrected rotational speed) received from the centrifugal pump control amount calculation unit **243**.

Hereinafter, an operational sequence in a case where the control unit **240** of the artificial heart and lung apparatus **200** of the second embodiment does not perform a correction process will be described with reference to FIG. 7. FIG. 7 is a flowchart showing the operational sequence of the control unit **240** in a case where a correction process is not performed in the artificial heart and lung apparatus **200**.

(1) First, the control unit **240** receives a blood removal rate parameter signal (S31).

(2) Subsequently, the control unit **240** calculates a blood removal rate according to the received blood removal rate parameter signal (S32).

(3) Subsequently, the control unit **240** calculates a target blood transfer rate according to the blood removal rate calculated in S32 (S33).

(4) Subsequently, the control unit **240** receives a blood transfer rate parameter signal (S34).

(5) Subsequently, the control unit **240** calculates a blood transfer rate according to the received blood transfer rate parameter signal (S35).

(6) Subsequently, the control unit **240** compares the target blood transfer rate calculated in S33 to the blood transfer rate calculated in S35, calculates (the target blood transfer rate—the blood transfer rate), and determines whether the target blood transfer rate is greater than or equal to the blood transfer rate (S36).

If the target blood transfer rate is greater than or equal to the blood transfer rate (S36: Yes), the process proceeds to S37. If the target blood transfer rate is less than the blood transfer rate (S36: No), the process proceeds to S38.

(7) The control unit **240** calculates a control amount (increased rotational speed) for the centrifugal pump **220** according to a difference (=the target blood transfer rate—the blood transfer rate) calculated in S36 (S37).

If the target blood transfer rate is equal to the blood transfer rate, the control amount (increased rotational speed) becomes zero.

(8) The control unit **240** calculates a control amount (decreased rotational speed) for the centrifugal pump **220** according to a difference (=the target blood transfer rate—the blood transfer rate) calculated in S36 (S38).

(9) Subsequently, the control unit **240** outputs a signal which corresponds to the control amount calculated in S37 or S38, to the centrifugal pump **220** (S39).

If S39 is executed, the process proceeds to S31.

S31 to S39 are repeatedly executed at predetermined intervals until a surgery is complete and blood circulation ends.

Hereinafter, an operational sequence in a case where the control unit **240** of the artificial heart and lung apparatus **200** of the second embodiment performs a correction process will be described with reference to FIG. 8. FIG. 8 is a flowchart showing the operational sequence of the control unit **240** in a case where a correction process is performed in the artificial heart and lung apparatus **200**.

(1) First, the control unit **240** receives a blood removal rate parameter signal (S41).

(2) Subsequently, the control unit **240** calculates a blood removal rate according to the received blood removal rate parameter signal (S42).

(3) Subsequently, the control unit **240** calculates a target blood transfer rate according to the blood removal rate calculated in S42 (S43).

(4) Subsequently, the control unit **240** receives correction process data (S44).

(5) Subsequently, the control unit **240** calculates a corrected target blood transfer rate by correcting the target blood transfer rate according to the correction process data (S45).

(6) Subsequently, the control unit **240** receives a blood transfer rate parameter signal (S46).

(7) Subsequently, the control unit **240** calculates a blood transfer rate according to the received blood transfer rate parameter signal (S47).

(8) Subsequently, the control unit **240** compares the corrected target blood transfer rate corrected in S45 to the blood transfer rate calculated in S47, calculates (the corrected target blood transfer rate—the blood transfer rate), and

determines whether the corrected target blood transfer rate is greater than or equal to the blood transfer rate (S48).

If the corrected target blood transfer rate is greater than or equal to the blood transfer rate (S48: Yes), the process proceeds to S49. If the corrected target blood transfer rate is less than the blood transfer rate (S48: No), the process proceeds to S50.

(9) The control unit 240 calculates a control amount (increased rotational speed) for the centrifugal pump 220 according to a difference (=the corrected target blood transfer rate-the blood transfer rate) calculated in S48 (S49).

If the corrected/target blood transfer rate is equal to the blood transfer rate, the control amount (increased rotational speed) becomes zero.

(10) The control unit 240 calculates a control amount (decreased rotational speed) for the centrifugal pump 220 according to a difference (=the corrected target blood transfer rate-the blood transfer rate) calculated in S48 (S50).

(11) Subsequently, the control unit 240 outputs a signal, which corresponds to the control amount calculated in S49 or S50, to the centrifugal pump 220 (S51).

If S51 is executed, the process proceeds to S41.

S41 to S51 are repeatedly executed at predetermined intervals until a surgery is complete and blood circulation ends.

Since the control unit 240 performs adjustment such that the flow rate of blood to be transferred to the first blood transfer line 104 is synchronized with the flow rate of removed blood flowing through the blood removal line 101, the artificial heart and lung apparatus 200 of the second embodiment is capable of transferring the same amount of blood as the amount of removed blood to the patient P.

As a result, even if the blood removal rate changes, it is possible to ensure a suitable blood transfer rate corresponding to the blood removal rate, and to perform suitable blood circulation.

In the artificial heart and lung apparatus 200 of the second embodiment, the correction process setting unit 260 is provided, and the control unit 240 corrects a deviation between the measurement characteristics of the blood removal rate sensor 111 and the blood transfer rate sensor 112 according to correction process data input to the correction process setting unit 260. As a result, it is possible to efficiently synchronize the blood transfer rate of the centrifugal pump 220 with the blood removal rate.

In the artificial heart and lung apparatus 200 of the second embodiment, the centrifugal pump 220 is used as a blood transfer pump, and thus, it is possible to promptly transfer blood at a stable blood transfer rate.

In the artificial heart and lung apparatus 200 of the second embodiment, the blood removal regulator 121 is provided in the blood removal line 101, and thus, the blood removal rate is suitably adjusted.

The blood transfer regulator 122 is provided in the first blood transfer line 104, and is capable of preventing the back flowing of blood by blocking the first blood transfer line 104 when the centrifugal pump 220 stops.

The present invention is not limited to the embodiments, and changes can be made to the embodiments in various forms insofar as the changes do not depart from the concept of the invention.

In the artificial heart and lung apparatuses 100 and 200 of the embodiments, the blood transfer rate is synchronized

with the blood removal rate. Alternatively, the blood transfer rate may be adjusted to be in a specific range with respect to the blood removal rate.

In the embodiments, the artificial heart and lung apparatuses 100 and 200 respectively include the correction process setting units 160 and 260. Alternatively, setting as to whether the correction process setting units 160 and 260 are included may be arbitrarily performed.

In a case where the correction process setting units 160 and 260 are included, the correction process setting units 160 and 260 may be externally attachably included.

In the embodiments, the blood removal rate sensor 111 and the blood transfer rate sensor 112 which measure the flow speed of blood are respectively used as blood removal rate measurement means and blood transfer rate measurement means. Alternatively, a blood removal rate and a blood transfer rate may be measured by measuring a blood removal rate parameter (including a blood removal rate) other than a blood removal speed and a blood transfer rate parameter (including a blood transfer rate) other than a blood transfer speed.

In the embodiments, ultrasonic sensors are used as the blood removal rate sensor 111 and the blood transfer rate sensor 112. Alternatively, various well-known flow rate measurement means using laser, infrared light, or the like may be used instead of an ultrasonic sensor.

In the embodiments, the roller pump 120 and the centrifugal pump 220 are used as blood transfer pumps. Alternatively, other types of blood transfer pumps may be used.

In the first embodiment, flow rate adjustment means is not provided in the blood transfer line. Alternatively, flow rate sensors (flow rate parameter measurement means) such as ultrasonic sensors may be suitably provided in the first blood transfer line 104 and the second blood transfer line 106.

In the first embodiment, the blood removal regulator 121 is provided as flow rate adjustment means, and in the second embodiment, the blood removal regulator 121 and the blood transfer regulator 122 are provided as flow rate adjustment means. Alternatively, in the first and second embodiments, neither the blood removal regulator 121 nor the blood transfer regulator 122 may be provided. In a case where flow rate adjustment means is provided, setting as to whether either or both of the blood removal regulator 121 and the blood transfer regulator 122 are provided may be suitably performed, and portions of a blood removal line and a blood transfer line, in which the blood removal regulator 121 and the blood transfer regulator 122 are provided, may be suitably set.

Flow rate measurement means other than the blood removal regulator 121 and the blood transfer regulator 122 may be provided.

In the first and second embodiments, the blood removal regulator 121 and the blood removal rate sensor 111 are disposed in the blood removal line 101 in the listed sequence. Alternatively, the blood removal rate sensor 111 and the blood removal regulator 121 are disposed in the listed sequence.

In the second embodiment, the blood transfer regulator 122 and the blood transfer rate sensor 112 are disposed in the first blood transfer line 104 in the listed sequence. Alternatively, the blood transfer regulator 122 and the blood transfer rate sensor 112 may be disposed in the second blood transfer line 106 instead of the first blood transfer line 104. The blood transfer rate sensor 112 and the blood transfer regulator 122 may be disposed in the listed sequence.

In the embodiments, FIGS. 3, 4, 7, and 8 show examples of the flowcharts showing schematic steps of controlling the

roller pump **120** and the centrifugal pump **220** of the present invention. Alternatively, control may be performed via methods (algorithms) other than the methods shown in the flowcharts.

In the embodiments, a blood circulation system is applied to the artificial heart and lung apparatuses **100** and **200**. Alternatively, the present invention may be applied to an auxiliary circulation apparatus (blood circulation system) and the like, which does not include a reservoir and is used in a cardiac surgery operation, other than an artificial heart and lung apparatus.

INDUSTRIAL APPLICABILITY

In a case where a blood circulation system of the present invention circulates removed blood via a blood transfer pump, the blood circulation system is capable of stably transferring blood at a suitable flow rate.

REFERENCE SIGNS LIST

- P: patient (human body)
- 100, 200**: artificial heart and lung apparatus (blood circulation system)
- 101**: blood removal line
- 102**: reservoir
- 104**: first blood transfer line (blood transfer line)
- 105**: artificial lung
- 106**: second blood transfer line (blood transfer line)
- 111**: blood removal rate sensor (blood removal rate measurement means)
- 112**: blood transfer rate sensor (blood transfer rate measurement means)
- 120**: roller pump (blood transfer pump)
- 121**: blood removal regulator (flow rate adjustment means)
- 122**: blood transfer regulator (flow rate adjustment means)
- 140, 240**: control unit
- 160, 260**: correction process setting unit
- 220**: centrifugal pump (blood transfer pump)

What is claimed is:

1. A blood circulation system that can be connected to a human body, and transfers removed blood to the human body via a blood transfer pump, the system comprising:

- a reservoir that temporarily stores the removed blood;
- a blood removal line that transfers the removed blood to the reservoir;
- the blood transfer pump that transfers stored blood in the reservoir to the human body;
- a blood line that connects the reservoir and the blood transfer pump;
- a blood transfer line that transfers the stored blood in the reservoir, which is sent from the blood transfer pump, to the human body;
- a blood removal rate measurement means that is provided in the blood removal line upstream of the reservoir to measure a blood removal rate parameter of the removed blood flowing through the blood removal line; and
- a controller including a blood removal rate parameter signal receiver, the blood removal rate parameter signal receiver being connected to the blood removal rate measurement means,

wherein the blood removal line, the reservoir, the blood line, the blood transfer pump and the blood transfer line are connected in the listed sequence,

wherein the blood transfer pump is a roller pump, wherein the reservoir includes a tank therein and is a portion in which blood is open to a space, and wherein the controller is programmed to control a blood transfer rate of the blood transfer pump by controlling a rotational speed of the blood transfer pump with a control signal, such that a transfer rate of blood flowing through the blood transfer line is synchronized with a removal rate calculated from the blood removal rate parameter.

2. The blood circulation system according to claim 1, further comprising:

a correction process setting unit, wherein, according to correction process data input to the correction process setting unit, the controller performs correction such that the blood transfer rate of the blood transfer pump corresponds to the blood removal rate.

3. The blood circulation system according to claim 1, wherein a flow rate adjustment means is provided in the blood removal line.

4. The blood circulation system according to claim 1, wherein the blood line or the blood transfer line is provided with no flow rate sensor.

5. A blood circulation method using a blood circulation system that can be connected to a human body and that transfers removed blood to the human body via a blood transfer pump,

the blood circulation system comprising:
a reservoir that temporarily stores the removed blood;
a blood removal line that transfers the removed blood to the reservoir;

the blood transfer pump that transfers stored blood in the reservoir to the human body;

a blood line that connects the reservoir and the blood transfer pump;

a blood transfer line that transfers the stored blood in the reservoir, which is sent from the blood transfer pump, to the human body; and

a blood removal rate measurement means that is provided in the blood removal line upstream of the reservoir to measure a blood removal rate parameter of the removed blood flowing through the blood removal line,

wherein the blood removal line, the reservoir, the blood line, the blood transfer pump and the blood transfer line are connected in the listed sequence,

wherein the blood transfer pump is a roller pump, wherein the reservoir includes a tank therein and is a portion in which blood opens to a space,

the blood circulation method comprising:
calculating a removal rate from the blood removal rate parameter; and

controlling a blood transfer rate of the blood transfer pump by controlling a rotational speed of the blood transfer pump, such that a transfer rate of blood flowing through the blood transfer line synchronized with the removal rate.